



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4678]

Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) for six Camel Snus smokeless tobacco products submitted by R.J. Reynolds Tobacco Co.

DATES: Electronic or written comments on the applications may be submitted until [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]; however, FDA may modify the comment period by providing notice as described in section I.

ADDRESSES: You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's

Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-4678 for “Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit

two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any

M RTP unless an order issued by FDA under section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in an MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, R.J. Reynolds Tobacco Co., is seeking orders under section 911(g)(1) for each of the 6 products that are the subject of the submitted MRTPAs. A person seeking an order under section 911(g)(1) of the FD&C Act must show that the tobacco product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that the MRTPAs for the following products submitted by R.J. Reynolds Tobacco Co. have been filed and are being made available for public comment:

- MR0000068: Camel Snus Frost
- MR0000069: Camel Snus Frost Large
- MR0000070: Camel Snus Mellow
- MR0000071: Camel Snus Mint
- MR0000072: Camel Snus Robust
- MR0000073: Camel Snus Winterchill

In this document, FDA is announcing the availability of the applications for public comment. FDA will make any amendments submitted by the applicant available for public comment on a rolling basis. The applications will be available for public comment for 180 days from the date this notice is published; however, in the event that fewer than 30 days remain in the 180-day comment period when an amendment is posted, FDA will extend or reopen the comment period to allow for at least 30 days of public comment on the amendment. FDA believes that this comment period is appropriate given the volume and complexity of the applications being posted. FDA will notify the public about the availability of amendments to these applications and changes to related comment periods via the Agency's website and other means of public communication. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

## II. Electronic Access

Persons with access to the internet may obtain the documents at:

<https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/UCM564399.htm>.

Dated: December 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-27246 Filed: 12/18/2017 8:45 am; Publication Date: 12/19/2017]